Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: Options for the implementation of a claimer for efficacy assessed non-prescription medicines

May 2018

TGA Health Safety Regulation

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Contents

Purpose and scope

The purpose of this consultation is to provide an opportunity for consumers, health professionals and industry to comment on proposed changes to improve the transparency of medicine labelling. These changes are intended to help consumers make more informed healthcare decisions when self-selecting medicines.

In our February 2017 consultation paper, Reforms to the framework for complementary medicines: Assessment Pathway, we consulted on a proposal to allow sponsors to claim ('the claimer') that their complementary medicine has been assessed by the TGA for efficacy where that medicine has undergone pre-market assessment by the TGA. This was supported by the majority of respondents.

Through further targeted consultation with industry and consumer representative groups, we have now refined options for the claimer and options for its implementation. In this consultation we are seeking feedback on the following:

- the class or classes of medicines that should be allowed to carry an optional claimer
- options to implement the claimer as a visual identifier and/or label statement
- how the claimer can be used on medicine labels.

We will also conduct consumer focus group testing on the options presented in this paper to confirm whether our potential options will achieve the objectives of this reform.

Background

Review of Medicines and Medical Devices Regulation

The Expert Panel conducting the Review of Medicines and Medical Devices Regulation made 19 recommendations to improve the regulatory framework for complementary medicines manufactured, supplied and/or exported from Australia. On 15 September 2016, the Australian Government released its Response to the Review of Medicines and Medical Devices Regulation[1].

The Government has agreed to implement a new assessment pathway for listed complementary medicines that will sit between the existing registration and listing pathways. Medicines listed through the assessed listed medicines pathway will be included in the ARTG following self-certification of the safety and quality of the product, and TGA pre-market assessment of efficacy evidence supporting the proposed indications.

Introduction of the **assessed listed pathway** bridges the gap between the evidence requirements, costs and timeframes for the existing listed and registered medicines pathways. This will allow greater consumer access to a wider range of evidence-based products to self-manage their health.

The Panel also recommended that, where a medicine is listed in the ARTG under the assessed listed medicines pathway, the sponsor should be able to indicate on all promotional materials

[1] Commonwealth of Australia (Department of Health), Australian Government Response to the Review of Medicines and Medical Devices Regulation (September 2016) available at: <https://www.tga.gov.au/australian-government-response-review-medicines-and-medical-devices-regulation>.

and on the medicine label, that the efficacy of the product has been independently assessed for the approved indications by the TGA.

The Government accepted this recommendation in principle, noting that the design and use of promotional statements will require careful consideration by the TGA and further consultation with stakeholders.

Implementation of these recommendations is intended to:

- **support consumers** to make better informed health decisions by improving the transparency about the efficacy of complementary medicines
- **improve consumer awareness** of the different levels of assessment of complementary medicines undertaken by the TGA.
- provide an incentive to the industry to **improve the evidence base** for complementary medicines
- provide an **incentive** for sponsors to use the new assessment pathway by providing a positive marketing advantage through the introduction of a claimer

Introduction of a claimer

Do you support the introduction of a claimer?

The role of the Therapeutic Goods Administration

The framework for the regulation of medicines in Australia is complex. For information on the Therapeutic Goods Administration and how different types of medicines are classified and regulated, please see **Appendix 1**.

Which medicines can use the claimer?

For self-selected medicines, which include over-the-counter (OTC) and listed medicines (e.g. complementary medicines and sunscreens), the medicine label is perhaps the most important communication tool for product sponsors to convey the medicines attributes to the potential consumer. The label is also the primary source of information for consumers at the time of purchase.

Registered and listed medicines[2] can be presented to consumers side-by-side in retail outlets with the inclusion of an AUST R or AUST L number on the product label being the only way they can identify how the medicine has been assessed by the TGA. With the introduction of the new 'assessed listed' medicines pathway, some medicines will carry an AUST L(A) number to identify the level of assessment by the TGA. We are aware, however, that consumers have a limited understanding about the classification of different medicines and the different levels of assessment undertaken by the TGA. Introduction of the claimer is therefore a potential means to help consumers make more informed healthcare decisions by improving the transparency about the evidence for the efficacy for self-selected medicines at the point of sale.

[2] For more information on the difference between listed and registered medicines, please see **Appendix 1**.

While the Panel's recommendation only suggested that a 'claimer' should be introduced as an option for assessed listed complementary medicines, it is recognised that these medicines are likely to only comprise a small subset of medicines which have been pre-market assessed for efficacy by the TGA and are available for self-selection by consumers in retail outlets.

With this in mind, we are seeking stakeholder comment on whether the class of medicines that should be allowed to use the claimer should be expanded.

In all options below, inclusion of a claimer on a medicine's label following efficacy assessment by the TGA will be **optional** for the medicine sponsor.

Options for the classes of medicines that can use the claimer

Option 1 – Allow claimers to be used for assessed listed complementary medicines only

Under this option, a claimer would **only** be approved for **complementary medicines** pre-market assessed by the TGA under the new assessed listed medicines[3] pathway. Standard listed medicines that have undergone post-market evidence assessment would not be able to use a claimer. This is consistent with the recommendation made by the Expert Panel[4] which aims to provide an incentive to sponsors' to improve the evidence base for the complementary medicines sector.

While this would help consumers to make more informed decisions when choosing between standard listed complementary medicines and assessed listed complementary medicines, it may provide an unfair advantage for these products over other non-prescription medicines which have been pre-market assessed for efficacy by the TGA. This includes:

- OTC and registered complementary medicines
- other types of listed medicines that may, in future, choose the assessed listed medicines pathway, such as sunscreens.

This may confuse consumers at the point of sale, particularly where there are a range of complementary and OTC medicines that carry similar health claims.

Option 2 – Allow the claimer to be used for all assessed listed medicines

Under this option, the claimer would be approved for **all** products pre-market assessed by the TGA under the new assessed listed medicines pathway. Primarily these will be complementary medicines, but in future a small number of other products, such as sunscreens and dental products, could also be listed through the new pathway.

This would help consumers in making informed decisions when self-selecting listed medicines and provide an incentive for sponsors of listed medicines to use the new assessment pathway.

However, it may provide an unfair advantage for these products over other pre-market efficacy assessed medicines (such as OTC and registered complementary medicines) which would not be able to use the claimer.

[3] For information on assessed listed medicines, please see Appendix 1.
[4] Expert Panel, Review of Medicines and Medical Devices Regulation: Report to the Minister for Health on the Regulatory Framework for Medicines and Medical Devices (31 July 2015), p 38.

Option 3 – Allow the claimer to be used for all pre-market assessed medicines available for self-selection by consumers

Under this option, the claimer would not be limited to assessed listed medicines (either complementary medicines or all assessed listed medicines) and could instead be used by all medicines available for non-prescription use that have been pre-market assessed by the TGA for efficacy. This would include:

- registered **Schedule 3** OTC medicines
- registered **Schedule 2** OTC medicines
- **general sale** OTC medicines
- registered complementary medicines
- all listed medicines evaluated by the TGA under the new assessed listed pathway.

This would allow consumers to quickly and easily identify which medicines available for self-selection at common retail outlets have been pre-market assessed for efficacy by the TGA. This would also help remove confusion about the different classifications of medicines by the TGA and allow consumers to make a more informed decision at the point of sale.

As prescription medicines can only be accessed by consumers from a pharmacist after receiving a doctor's prescription (and are not available for self-selection) including a claimer for these products is likely to be of little value to consumers.

It is noted that, for similar reasons, the use of a claimer is also unlikely to be of significant value for Schedule 3 OTC medicines, as they require face-to-face contact between pharmacist and consumer to be supplied. However, under this option, sponsors of registered Schedule 3 OTC medicines could use a claimer if they wish to do so.

Options for use of a claimer

Which class or classes of medicines should the option of a claimer apply to?

What will the claimer look like?

To achieve the objective of improving the transparency about medicine labels and assisting consumers to make more informed healthcare decisions, the claimer:

- must be readily **understood** by the average consumer
- must be informational rather than promotional and clearly identify **intention** of the scheme
- must not imply that other self-selectable pre-market assessed medicines without a claimer are **less effective**
- should reflect the level evaluation undertaken by the TGA.

The TGA previously consulted on the introduction of a claimer in the February 2017 public consultation, Reforms to the framework for complementary medicines: Assessment Pathway.

Following this consultation, we propose that there will be two ways in which the claimer may be implemented. These are:

- With a unique ARTG identifier on the main label and packaging of the medicine **and**
- a TGA approved 'symbol' or 'visual identifier' **and/or**
- a TGA approved label statement

This consultation builds on these proposals by outlining implementation proposals and design options for each of these.

Unique ARTG identifier

Medicines that are supplied in Australia must apply a unique registration or listing number on the main label of the product[5]. Currently, this is the only way consumers can identify what level of assessment has been undertaken by the TGA. The ARTG number must be included on a medicine label as follows:

- Registered medicines must include the registration number preceded by the ARTG identifier, **AUST R**.
- Standard listed medicines (i.e. those that are not assessed pre-market) must include the listing number preceded by the ARTG identifier, **AUST L**.

In keeping with this current system of medicine identification, assessed listed medicines will be assigned a new unique ARTG identifier, **AUST L(A)**. An example is show below in **Table 1**.

Table 1 – AUST L(A) label mock up

Example 1	Example 2
	

[5] The requirement for medicines that are on the ARTG to have on their labels the relevant registration number or listing number is specified in regulation 15 of the *Therapeutic Goods Regulations 1990*. This prescribes where on a medicine label the numbers must be placed and how they should be displayed.

Options for the visual identifier

Implementation of a visual identifier in addition to the unique ARTG identifier would give much greater transparency for consumers on which medicines have been assessed by the TGA and which medicines are self-certified by the product sponsor[6].

We are aware that consumers have a limited understanding about the risk-based classification of medicines and are generally unaware of the presence or meaning of ARTG identifiers on medicine labels. A visual identifier would allow consumers to quickly and easily identify medicines that have been assessed by the TGA pre-market at the point of sale.

The key criteria identified above were used to develop the visual identifiers proposed below.

Option 1 – 'TGA assessed'

This design (see **Table 2**) would allow consumers to clearly identify self-selected products which have been pre-market assessed by the TGA. It clearly identifies who is the behind the scheme.

However, it would also require the use of a label statement to ensure that consumers are aware of the level of assessment undertaken by the TGA as this is not specified under this option.

Table 2: Option 1 for the visual identifier

Prototype design	Mocked-up label
	

Option 2 – 'TGA efficacy assessed'

This design (see **Table 3**) would also allow consumers to clearly identify self-selected products which have been pre-market assessed by the TGA for efficacy and may eliminate the need for a supporting label statement. It would also clearly identify who is the behind the scheme.

[6] Expert Panel, pp. 38-39.

Table 3: Option 2 for the visual identifier

Prototype design	Mocked-up label
TGA efficacy assessed	

Visual identifier

What is your preferred option for the visual identifier?

Options for the wording of the label statement

Implementation of a label statement, which could be used in conjunction with the ARTG identifier and visual identifier, may provide additional transparency about the level of assessment undertaken by the TGA. If used, such a statement needs to be succinct so that it can be easily understood by average consumers.

The proposed options for the label statement are provided below.

Option 1 – No label statement

Under this option, no label statement would be included on the medicine label. This may be appropriate if the visual identifier selected was able to clearly identify who is behind the scheme and if the medicine has been assessed by the TGA for efficacy (e.g. Option 2 above).

Option 2 – 'Evidence for the approved indications has been assessed by the TGA'

This option clearly identifies who is the behind the scheme and its intention in simple and easy to understand language. It is succinct making it more likely to be easily understood by consumers.

Option 3 – 'Efficacy evidence has been assessed by the TGA'

This option clearly identifies who is the behind the scheme and its intention in simple and easy to understand language.

It accurately reflects the level of evaluation undertaken by the TGA and is succinct, making it more likely to be easily comprehended by consumers. However, we are aware that the concept of 'efficacy' may not be well understood by consumers.

Label statement

Which is your preferred option for the label statement?

Do you have an alternative?

How can the claimer be used on medicine labels?

Labels are intended to communicate information that is essential to consumers, prescribers, and dispensers on how to use medicines safely and effectively. It also provides details about the intended use of a medicine so consumers can ensure they have selected the right product for their needs.

To achieve its intended outcome, the claimer must be presented in a way that is easy to find and understand.

TGA proposal for the colour of the claimer

We propose that the colour of the visual identifier and label statement must be standardised to allow for easy identification across different product types.

Consistent with the non-prescription medicines labelling requirements[7], the colour of the claimer must contrast strongly with the background it is printed on. This is extremely important for readability, especially as there is lots of other health information presented on a medicine's label.

In order to ensure consistency with the labelling requirements, we propose the following:

- the visual identifier must be in **black ink** on a **white** background and surrounded by a **black** outline. This is shown in **Table 4**.
- if implemented, the label statement must be in a colour that **contrasts strongly with the background** it is printed on. The font style and colour should be consistent with other label text and must not interfere with the legibility of mandatory label information.

[7] The Therapeutic Goods Order 92 – Standards for labels of non-prescription medicines (TGO 92) sets the requirements for labels of non-prescription medicines (listed, registered complementary and OTC medicines).

Table 4: Standardised colour of the visual identifier

Example 1	Example 2
	

Using a standardised colour for the visual identifier would help build consumer recognition in the scheme, particularly as it would be presented in the same colour across different medicine types.

It would also help the claimer to strongly contrast against other information included on the medicine label.

Colour of the claimer

Should the colour of the claimer be standardised?

TGA proposal for the size of the claimer

The size of the claimer must not detract from mandatory product information. This is crucial as the claimer needs to be balanced against the other information presented on the main label and primary pack to assist consumers in selecting and using a medicine.

Unlike other critical information, the claimer provides information based messaging for the consumer. With this in mind, we propose the following:

- The size of the text included in the visual identifier and the text of the label statement must not be smaller than **1.5mm** as is consistent with current labelling requirements.
- The text size must not be larger than the text size for the names and amounts of active ingredients.

Size of the claimer

Do you agree with the proposed size limits for the claimer?

Options for the location of the claimer

The location of the claimer on the medicine label must be directly related to the objectives of the recommendation and be consistent with existing labelling requirements.

Currently, essential and risk based messaging is prioritised for inclusion on the **main label**[8] of a medicine. The information that must be included on the main label includes:

- the name of the medicine
- the active ingredients included in the medicine and their quantities or proportions
- the name of the dosage form (for example, oral or topical)
- the quantity of the medicine (for example, the number of tablets included in the packet)

To ensure their safe use, some medicines that are self-selected by consumers must also have critical health information (CHI) included on their label. This information does not need to be included on the main label but must be present on the **primary pack**.[9] The CHI includes information such as:

- the active ingredients included in the medicine
- the indications or claims for the medicine (for example, 'relieves headaches')
- any warning associated with the use of the medicine (for example, 'not to be used in children)
- any directions associated with its use (for example, 'take two tablets daily')

With this in mind, we have provided two options for the location of the claimer on medicine labels.

Option 1 – The claimer must be included on the main label

Under this option the claimer must be included on the main label. This would allow for the claimer to be quickly and easily identified by consumers at the point of sale.

Option 2 – The claimer must be included on the primary pack

Under this option the claimer does not need to be included on the main label.

While including the information on a back or side panel will ensure that the main label does not become overcrowded, a consumer would have to inspect the entire primary pack to determine whether or not the medicine had been pre-market assessed for efficacy by the TGA.

Location of the claimer

What is your preferred option for the location of the claimer?

[8] The **'main label'** (defined in Section 6 of TGO 92) is the portion of the label where the name of the medicine is more or most conspicuously shown.
[9] The **'primary pack'** (as defined in the *Therapeutic Goods Act 1989*) means the complete pack in which the medicine, or the medicine and their container, are to be supplied to consumers.

How will the claimer be implemented?

To ensure consistency with the implementation of other MMDR Recommendations, the claimer is proposed to be available to align with the first successful application for an assessed listed medicine.

The new pathway for assessed listed medicines commenced in **March 2018**. It anticipated that the first assessed listed medicine could be approved as early as the 3rd quarter of 2018.

More information on the assessed listed pathway is available on the TGA website.

It is anticipated that once the claimer designs and implementation approach are finalised, and if the option of a claimer is extended to registered self-selected medicines, sponsors of those products will be able to apply for approval to use the claimer as a variation (or change) to the medicine label.

Approval and use

Given that the inclusion of a claimer on a medicine's label following efficacy assessment by the TGA will be optional for the medicine sponsor, we propose the claimer will be approved via a **condition of the product approval**.

Advantages of this approach include:

- It would provide mechanism to revoke an approval where the sponsor does not hold / no longer holds information or evidence that supports the product indications, or where TGA determines that the evidence no longer supports the indication, for example following receipt of a complaint or outcomes of new research.
- It would provide a mechanism to cancel a medicine, where the medicine label or promotional material doesn't comply with the condition.

Implementation through an express provision of approval could also be achieved through amendment to the Therapeutic Goods Regulations 1990. However, this will only be done where absolutely necessary.

Education

In order to foster improved consumer understanding of the medicines regulatory framework, introduction of the claimer will be supported by:

- a consumer education and awareness program
- updated industry and consumer guidance on the TGA website

TGA will conduct further consultation, in conjunction with consumer groups, on ways to better educate consumers about the medicines listing system, including about the difference between listed complementary medicines and registered medicines. Because the system is undergoing change at present, the launch of these programs will be timed to align with the implementation of groups of MMDR review reforms.

Appendix 1: The role of the Therapeutic Goods Administration

Who we are and what we do

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose. These include goods Australians rely on every day, such as vitamin tablets and sunscreens, through to goods used to treat serious conditions, such as prescription medicines, vaccines, blood products and surgical implants.

Generally any product for which therapeutic claims are made must be entered in the Australian Register of Therapeutic Goods (ARTG) before it can be legally supplied in Australia.

When determining whether or not to include a therapeutic good in the ARTG, the TGA considers[10] the safety, quality and efficacy of the product. These are explained in **Table 5**.

Table 5: Understanding safety, quality and efficacy

Evaluation type	Definition
Safety	To ensure that the benefits of taking a medicine outweigh any risks associated with its use.
Quality	To ensure that the medicine meets all necessary standards. For example, that it is made in accordance with the principles of Good Manufacturing Practice.
Efficacy	Establishing a causal relationship between a treatment and its intended therapeutic effect (i.e.: that it does what it claims to do) in a controlled **clinical setting**.

Risk based approach to regulation

The Australian regulatory regime for therapeutic goods regulates products according to risk. By this we mean that our scientific assessments and decision-making are intended to ensure that the benefits of a medicine outweigh any risks associated with its use. The identified level of risk determines:

- the amount and type of information we need to review
- the degree of scrutiny necessary before the product can be made available in Australia
- the level of safety monitoring once it is available.

The level of risk also determines the manner in which the public can gain access to that product. For example, many lower risk products such as herbal and multi-vitamin products may be safely

[10] Depending on the risk posed by the medicine, the TGA will either individually assess a medicine to check if it meets the criteria for safety, quality and efficacy (registered medicine) or not (listed medicine).

sold in supermarkets, whereas higher risk medicines such as blood pressure medications may only be supplied with a prescription from a suitably qualified health professional.

Medicines and TGA classifications

To support this risk-based approach, Australia has a two-tiered system for the regulation of medicines. Within the regulatory framework, medicines are classified as either:

- higher risk medicines which are **registered** in the ARTG
- lower risk medicines that are **listed** in the ARTG.

The following risk criteria to determine whether a certain type of medicine must be registered or listed:

- the ingredients, including whether the medicine contains a substance scheduled in the Standard for the Uniform Scheduling of Medicines and Poisons (the Poison Standard);
- the dosage and dosage form of the product (for example, whether the medicine is an injectable or a cream applied directly onto the skin)
- the promotional or therapeutic claims or indications made for the product (for example 'relieves headaches').

Whether a medicine is classified as registered or listed determines the level of assessment undertaken by the TGA. This outlined below.

Registered medicines

All registered medicines are fully assessed by the TGA for quality, safety and efficacy. After an evaluation of data, a TGA delegate considers the overall application and either grants approval to include the product in the ARTG for specified use, or rejects the application. There are three types of registered medicines.

Prescription medicines

Prescription medicines contain ingredients included in **Schedule 4, 8 and 9** to the Poison Standard. You need a doctor's prescription to buy prescription medicines and they are dispensed by a pharmacist. Otherwise, only authorised health care professionals can supply them, such as in a hospital setting.

Examples of prescription medicines include contraceptive pills, antibiotics and strong painkillers.

Over-the-counter (OTC) medicines

OTC medicines do not require you to have a prescription. However, there are controls around how they can be made available to consumers. There are three types of OTC medicines:

- **Pharmacist-only medicines** (included in **Schedule 3** to the Poisons Standard). These medicines can only be supplied by a pharmacist require face-to-face contact between pharmacist and consumer.
- **Pharmacy medicines** (included in **Schedule 2** to the Poisons Standard). These medicines can be supplied where advice or counselling from a pharmacist is available if required by the consumer.

- **General sales medicines** (not included in any of the Schedules to the Poisons Standard). These are available for purchase in supermarkets, health food stores and other retailers.

Examples of OTC medicines include cough and cold remedies, anti-fungal treatments and non-prescription analgesics such as aspirin and paracetamol.

Registered complementary medicines

Registered complementary medicines are considered to be relatively higher risk than listed medicines, based on their ingredients or the indications made for the medicine. Registered complementary medicines may be subject to the conditions of a schedule (other than **Schedules 4, 8 and 9**) or an appendix of the Poisons Standard.

As is the case for OTC medicines, you can buy registered complementary medicines for self-treatment from pharmacies, with selected products also available in supermarkets, health food stores and other retailers.

Examples of registered complementary medicines include iron supplements to treat iron deficiency anaemia.

Listed medicines

Listed medicines are lower risk and, as such, do not undergo a full pre-market assessment by the TGA before they are entered in the ARTG.

The majority of medicines listed in the ARTG are **complementary medicines**. Complementary medicines contain ingredients such as herbs, vitamins, minerals, nutritional supplements, as well as homoeopathic and certain aromatherapy preparations. However, complementary medicines are just a subset of listed medicines, with products such as **sunscreens** and **dental products** also listed in the ARTG.

You can buy listed medicines for self-treatment from pharmacies, with selected products also available in supermarkets, health food stores and other retailers.

The TGA now has **two listing pathways** for sponsors to list a medicine in the ARTG.

Standard listed medicines

Medicines can be listed in the ARTG following a self-certification by the sponsor of the safety, quality and efficacy of the product. Unlike other medicines, standard listed medicines are not assessed by the TGA before they can be sold to the general public. However, the TGA has a number of controls set up to ensure their safe and effective use. These include that the products must:

- only contain certain low-risk ingredients that included in the Permissible Ingredients Determination[11] which have been pre-approved by the TGA
- be manufactured in accordance with the principles of Good Manufacturing Practice[12] (GMP)
- only make indications relating to health maintenance, health enhancement and certain non-serious, self-limiting conditions that are included in the Permissible Indications Determination[13] which have been pre-approved by the TGA.

[11] This determination specifies the ingredients that are permitted for use in a medicine listed in the ARTG under subsection 26BB of the *Therapeutic Goods Act 1989* and any requirements associated with their use.
[12] Good Manufacturing Practice (GMP) describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality.

As standard listed medicines are self-certified by the medicine sponsor, the TGA has a rigorous **post-market monitoring** system for standard listed medicines. Each year, a proportion of listed medicines are reviewed by the TGA to ensure they meet all the regulatory requirements. Medicines which are found to be non-compliant may be cancelled from the ARTG and can no longer be sold in Australia.

It is important to note that **sunscreen products** are regulated slightly differently to other listed medicines. Because of the importance of sun protection in Australia, sunscreens can only contain certain active sunscreening ingredients that are included in the list of sunscreening agents[14] as part of the permissible ingredients determination. All sunscreens must also comply with the requirements set out in the Australian/New Zealand Standard[15]. The requirements of the Standard also include that the efficacy of each sunscreen product is tested to determine the sun protection factor (SPF), which must be printed on the product label.

Assessed listed medicines

In **March 2018** the TGA implemented a new 'assessed listed medicines' pathway for sponsors to enter their products in the ARTG. Medicines listed through the assessed listed medicines pathway will be included in the ARTG following sponsor self-certification of the safety and quality of the product, coupled with TGA pre-market assessment of the efficacy evidence supporting the proposed indications.

The **assessed listed pathway** allows sponsors to apply for indications are **not** included on the Permissible Indications Determination, but in all other respects the medicines meet the eligibility criteria for standard listed medicines (e.g. must only contain only permitted ingredients and be manufactured in accordance with GMP).

Because the Permissible Indications Determination contains all indications that can currently be made by sunscreens marketed in Australia, in practice we expect no or very few sunscreens to be listed through the new pathway, but it is not beyond the realms of possibility.

More information on the assessed listed pathway is available on the TGA website.

[13] This determination specifies the indications that are permitted for use in a medicine listed in the ARTG under subsection 26BB of the *Therapeutic Goods Act 1989* and any requirements associated with their use.
[14] Australian regulatory guidelines for sunscreens (ARGS), version 1.1 (January 2016), available at: <https://www.tga.gov.au/publication/australian-regulatory-guidelines-sunscreens-args>.
[15] The current standard is AS/NZS 2604:2012, Australian and New Zealand Standard, Sunscreen products - Evaluation and classification.

Version history

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